WORK PLAN AND METHODOLOGY :

1. **Literature Review:**

   Literature review will be done by referring International and National Journals, official Books and Internet.

2. **Selection of Therapeutic Proteins and Excipients.**

   Therapeutic proteins will be selected as drug candidates who have high molecular weight and high solubility in water but less stability in aqueous medium.

3. **Procurement of Therapeutic Proteins and Excipients.**

   Therapeutic Proteins and Polymers will be procured from various Pharmaceutical Industries. Excipients will be procured from authorized suppliers.

4. **Experimental**

   - **Characterization of Therapeutic Proteins:**

     a. **UV Spectroscopy:**

     UV Spectroscopic studies will be done by using UV Spectrophotometer.

     b. **IR Spectroscopy :**

     IR Spectroscopic studies will be performed by using IR Spectrophotometer.

     c. **Stability study:**

     Stability study will be carried out by using Stability Chamber over various time intervals of 0 and 24 hrs.

     d. **Bioassay:**

     Bioassay of Therapeutic Proteins will be carried out by using UV Spectrophotometric Bioassay Method.

     e. **Partial characterization:**

     Partial characterization of Therapeutic Proteins will be done by SDS PAGE, Gelatin Zymogram Technique.

   - **Characterization of Polymers and Excipients:**

     a. **Physical properties:**

     Physical Properties of Polymers and Excipients will be done by using Scanning Electron Microscopy.

     b. **IR Spectroscopy :**

     IR Spectroscopy will be carried out by using IR Spectrophotometer

c. **Melting points/ Boiling Points :**

Melting points and Boiling Points will be determined by using Melting Point Apparatus.

d. **Viscosity:**

Viscosity will be determined by using Brookfield Viscometer.

- ⊙ Preparation of Multiparticulate Drug Delivery Systems (MDDS) of therapeutic proteins using various polymers.
- ⊙ Enteric Coating to formulations by Spray Drying Method using R and D Coater.

5. **Evaluation**

- ⊙ **Morphology and Particle Size analysis:**

  Morphology and Particle Size analysis will be studied by Scanning Electron Microscopy and Vernier Caliper.

- ⊙ **Percentage yield and Entrapment Efficiency (Drug Loading):**

  Percentage yield and Entrapment Efficiency will be calculated by using formula given in literature.

- ⊙ **Acidic degradation protection assay:**

  Acidic degradation protection assay will be studied by using UV Spectrophotometric Assay Method.

- ⊙ **Polymer water uptake studies:**

  Polymer water uptake will be determined by equilibrium weight gain method.

- ⊙ **In - *vitro* release pattern of formulations.**

  In vitro drug release studies will be carried out using the rotating basket method specified in USP XXIII dissolution apparatus (Apparatus I, 100 rpm, 37 ± 0.5 0 C). The drug release studies will be carried in 900ml medium.

- ⊙ **Stability Studies of optimized formulations:**

  Stability Studies of optimized formulations will be performed as per ICH guidelines.

- ⊙ **In – *vivo* studies of optimized formulations:**

  In – *vivo* studies of optimized formulations will be carried out by selecting appropriate Animal Model.

6. **Result and Discussion.**
7. **Summary and Conclusion.**